



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

| APPLICATION NO.  | FILING DATE        | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.                           | CONFIRMATION NO.                          |
|--|--------------------|----------------------|---|---|
| 10/554,185   | 10/21/2005         | Mark T Bilodeau      | 21377YP                                       | 1883                                      |
| 210<br>MERCK AND CO., INC<br>P O BOX 2000<br>RAHWAY, NJ 07065-0907 | 7590<br>11/21/2008 |                      | <div>EXAMINER</div> <div>CHANG, CELIA C</div> |   |
|  |                    |                      | <div>ART UNIT</div> <div>1625</div>           | <div>PAPER NUMBER</div>                   |
|  |                    |                      | <div>MAIL DATE</div> <div>11/21/2008</div>    | <div>DELIVERY MODE</div> <div>PAPER</div> |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/554,185

**Applicant(s)**

BILODEAU ET AL.

**Examiner**

Celia Chang

**Art Unit**

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 9-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Applicant's election of Group I, species of first compound of claim 4 in the reply filed on Aug. 12, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Further applicants provided no evidence that the diversified method, multiple component composition or method of use are inexorably linked to the core structure of the compounds. It is well established in the field of akt enzyme system art that multiple isozymes existed with distinct and independent functional activity (see Tessier et al.). The specification provided on pages 43-49 description of assay procedures without any data supporting an inexorable link between the activity of the compound and the down stream functional relationship. Therefore, none of the method of use claims is considered rejoinable.

The requirement is still deemed proper and is therefore made FINAL.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

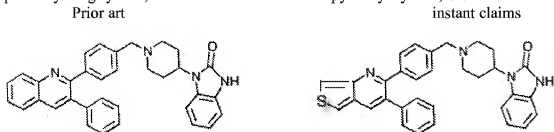
Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bilodeau et al. US 7,223,738 in view of King et al., Webber et al. supplemented with Patani.

Determination of the scope and content of the prior art (MPEP §2141.01)

Bilodeau et al. '738 disclosed isosteric analogue of the instant claims. Specific examples analogous to the scope of the instant claims are found at columns 111-112 table 6, second compound. The reference also disclosed the optional substitutions on the Markush ring system.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the prior art compound and the instant claims is that instead of a quinolinyl ring system, the instant claims are thienopyridinyl system, i.e.



Guided by the exemplified species, the reference provided modification of various substitutions on the disclosed ring systems.

King et al. taught that thienyl ring system and phenyl ring system are isosteric structure (see p. ). Webber et al. taught that the quinolinyl and thienopyridinyl ring system being isosteric because of the configurational similarity (see whole article). Patani et al. described that such isosteric modification of lead compounds is a design choice to medicinal chemists.

Finding of prima facie obviousness—rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art is deemed to be aware of all the relevant art in the field. The above references placed the art active compound having a quinolinyl ring in artisan's possession. The modification of a proven compound with the design choice of isosteric replacement using a well known functional equivalency of the ring system is prima facie obvious since such replacement modification is well recognized in the art to be useful in obtaining more compounds with similar activity.

3. Claims 1-8 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 7,223,738 in view of King et al., Webber et al. supplemented with Patani. Although the conflicting claims are not identical, they are not patentably distinct from each other for the same rational of finding the described compounds prima facie obvious as delineated in section 2.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duggan et al. US 7,399,764 in view of Bilodeau et al. US 7,223,738.

*Determination of the scope and content of the prior art (MPEP §2141.01)*

Duggan et al. '764 disclosed analogous compounds having akt activity and a structurally close species was found on col. 35-36 formula and compound I-4. The reference also disclosed the optional substitutions on the Markush ring system.

*Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)*

The difference between the instant claims and the prior art compound is that instead of a diazopyrazinyl or thienopyrazinyl ring systems, the instant compounds are drawn to diazopyridinyl or thienopyridinyl rings. Bilodeau et al. '738 taught that pyrazinyl bicyclic and pyridinyl bicyclic ring systems are optional choices for such akt compounds (see col. 6 formula A-1 vs col. 8, formula B).

*Finding of prima facie obviousness—rational and motivation (MPEP §2142-2143)*

One having ordinary skill in the art is deemed to be aware of all the relevant art in the field. The above references placed the akt active compounds with the design choices in structural attributes in the possession of one skilled in the field. The modification of one proven compounds with attributes of other proven compounds is prima facie obvious design choice. Absent of unexpected results, there is nothing unobvious in choosing some among many guided by the well delineated and exemplified attributes of the prior art.

5. Claims 1-8 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 7,399,764 in view of claim 1 vs 2 of US Patent No. 7,223,738. Although the conflicting claims are not identical, they are not patentably distinct from each other for the same rational of finding the described compounds prima facie obvious as delineated in section 4.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang  
Nov. 19, 2008

/Celia Chang/  
Primary Examiner  
Art Unit 1625

Application/Control Number: 10/554,185  
Art Unit: 1625

Page 6